#### UNITED STATES COURT OF APPEALS

#### FOR THE SIXTH CIRCUIT

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Filed: August 20, 2020

Mr. Kevin L. Murch Perez & Morris 8000 Ravine's Edge Court Suite 300 Columbus, OH 43235

Re: Case No. 20-3875, In re: State of OH Board of Pharmacy

Originating Case No: 1:17-md-02804 : 1:18-op-45032 : 1:18-op-45079

#### Dear Counsel:

The petition for writ of mandamus has been docketed as case number 20-3875 with the caption listed above. If you have not already done so, you must mail a copy of the petition to the lower court judge and counsel for all the other parties.

The filing fee for the petition is \$500, which is payable to the Clerk, Sixth Circuit Court of Appeals. If you wish to seek a waiver of the filing fee, a motion for pauper status with a completed financial affidavit is due by **September 3, 2020**. The financial affidavit is available at <a href="https://www.ca6.uscourts.gov">www.ca6.uscourts.gov</a>.

Counsel for petitioner must file an Appearance of Counsel form and, if not admitted, apply for admission to the 6th Circuit Bar by **September 3, 2020**. The forms are available on the court's website.

The district court judge to whom this petition refers has been served with this letter.

Sincerely yours,

s/Amy E. Gigliotti Case Management Specialist Direct Dial No. 513-564-7012

cc: Ms. Sandy Opacich

# In The United States Court of Appeals For the Sixth Circuit

In re: State of Ohio Board of Pharmacy,	
Petitioner.	Case No United States District Court for the Northern
[County of Lake, Ohio, et al. v. Purdue Pharma, L.P, et al]	District of Ohio, Eastern Division.
[The County of Trumbull, Ohio v. Purdue Pharma et al.]	[MDL No. 2804; Case No. 18-op-45032 and 18-op-45079]
{Relates to: National Prescription Opiate	

# PETITION FOR A WRIT OF MANDAMUS TO THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO AND MOTION FOR STAY OF DISTRICT COURT ORDER PENDING MANDAMUS

Litigation}

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### I. Introduction and Summary of Argument

The State of Ohio Board of Pharmacy ("the Board") is seeking a writ of mandamus under 28 U.S.C. § 1651 and F.R.A.P. 21 holding that the Northern District of Ohio ("the district court") abused its discretion in requiring the Board to disclose confidential information found in the Ohio Automated Rx Reporting System ("OARRS") containing the sensitive health information of over seven million Ohioans and in failing to certify the issues for appeal. The Board also respectfully requests that this Court promptly stay the district court's order compelling the Board to turn over OARRS data pending disposition of this petition.

OARRS is a database operated by the Board that allows prescribers and pharmacies to monitor the dispensing of controlled substances to their patients for suspected abuse or diversion (i.e., channeling drugs into illegal use). For over the last decade, pharmacists around the state have entered confidential and privileged information about their dispensation of controlled substances to Ohio citizens into OARRS. In the underlying case, the district court has ordered the Board to essentially produce the entire OARRS database to third parties who are unauthorized by law to receive such data which includes disclosure of the sensitive health information of over seven million Ohioans. The specific information the district court has directed the Board to produce would provide the means to unlock the identity of millions of people's prescribing history.

The Board has made repeated and strenuous objections that the OARRS data is confidential and privileged pursuant to both Ohio and federal law<sup>1</sup> and therefore should not be disclosed. These arguments have been rejected by the district court. Based upon the broad scope and seriousness in ordering this disclosure, the Board is entitled to request a review from this Court of the district court's order. In the same entry ordering the disclosure of the OARRS data, the district court also *sua sponte* denied the Board the right to appeal the district court's order. Thus, in order to protect the confidential and privileged OARRS data, the Board's only recourse was to pursue this mandamus action.

A party seeking mandamus must demonstrate that it has a "clear and indisputable" right, there are "no other adequate means" of relief, and the writ is otherwise "appropriate under the circumstances." *Cheney v. United States Dist. Court D.C.*, 542 U.S. 367, 380-81 (2004). The district court left the Board with "no other adequate means" of relief when it refused to certify the issue for appeal under 28 U.S.C. §1292. Without the right to appeal, the Board has no relief to seek review of the district court's abuse of discretion in ordering the disclosure of the confidential

<sup>&</sup>lt;sup>1</sup> The data that is contained in OARRS is expressly confidential under state law – specifically O.R.C. 4729.80 and 4729.86. The Board is only authorized to release OARRS information for certain limited reasons and Ohio law expressly prohibits the use of OARRS information in civil cases. There appears to be no dispute that this discovery issue turns on interpreting this rule because the case before the district court was solely premised on Ohio nuisance law.

and privileged information. A review of the underlying district court's order is "appropriate under the circumstances" as this involves the disclosure of sensitive health information of millions of Ohio citizens. This is just one "track" of claims by nearly 2,000 political subdivisions that have been consolidated in the district court as multi-district litigation ("MDL"). The district court order will be setting important - and arguably improper - precedent that will not only affect the other pending MDL matters in Ohio, but the similar pending national cases as well. The Board is entitled to a writ of mandamus and a stay until this Court reviews the district court's order.

#### II. Statement of Facts

#### The OARRS Program and its Strict Limitations.

OARRS records are highly confidential, and the Board tightly controls access. *See* Acceptable Use Policies at https://www.ohiopmp.gov/Documents.aspx. The confidentiality and security of data is central to the operation of all prescription drug monitoring programs ("PDMP"). *See Whalen v. Roe*, 429 U.S. 589, 600-602 (1977). OARRS includes a patient database which contains records of all controlled substances dispensed to outpatients. The patient database has a portal limited only to an authorized user, which is intended to be used by both law enforcement and other statutorily-designated categories of users to ensure compliance with Ohio law. *See* https://www.ohiopmp.gov/. In a typical patient database transaction, a patient

presents a prescription for a controlled substance to a licensed pharmacist in the state of Ohio. After dispensing that medication, the pharmacist logs the following information into OARRS pursuant to Ohio Administrative Code 4729:8-3-02:

- 1. Pharmacy drug enforcement administration registration number
- 2. Pharmacy name
- 3. Pharmacy address
- 4. Pharmacy telephone Number
- 5. Patient full name
- 6. Patient residential address
- 7. Patient telephone
- 8. Number Patient date of birth
- 9. Patient gender
- 10. Prescriber's full name (first name and last name)
- 11. Prescriber's drug enforcement administration registration number
- 12. Date prescription was issued by the prescriber
- 13. Date the prescription was dispensed or sold by the pharmacy

- 14. Indication of whether the prescription dispensed is new or a refill
- 15. Number of the refill being dispensed
- 16. Nation drug code of the drug dispensed
- 17. Number of refills authorized by the prescriber
- 18. Quantity of the drug dispensed
- 19. Number of days' supply of the drug dispensed
- 20. Serial or prescription number assigned to the prescription order
- 21. Source of payment for the prescription
- 22. Pharmacy national provider identification (NPI) number
- 23. Prescriber's national provider identification (NPI) number
- 24. ICD-10-CM or CDT diagnosis/procedure code

Access to the patient database is tightly controlled. Limited access is granted to pre-approved individuals for specific authorized purposes; the scope of access is

limited to only that information which would be appropriate for the particular user to access. *See* O.R.C. 4729.80(A). In the case of law enforcement officials, for instance, authorization to access an individual's OARRS data is only granted after entry of a case number and approval for access by their supervisor. *See* Ohio Administrative Code 4729-37-08(B); *State v. Meyers*, 12th Dist. App. No. CA2014-02-002, 2015-Ohio-160, 27 N.E.3d 895, ¶ 13. Even then, the official would only have access to the records necessary to complete that particular investigation.

The same access restrictions are true of any other type of user. Each user may access only the information necessary to perform their official duties. For instance, among those granted access are health care professionals who prescribe reportable medications and pharmacists who dispense those medications. The physicians may only access those records directly related to patients presently under their care or to their own prescribing. O.R.C. 4729.80(A)(5). When the Board discovers abuse or misuse of the database, it both refers violators for criminal prosecution and revokes or restricts access for egregious abuses of the database. Improper access to, or use or distribution of, information contained within the OARRS database can be punishable by a felony. *See* O.R.C. 4729.99(J); *Meyers*, 27 N.E.3d at 899.

### The Board Provided A "Research Extraction" to the Pharmacy Defendants.

Previously in the MDL, the Board provided a "research extraction" of the OARRS data to McKesson – one of the defendants that settled. Permitted by O.R.C.

4729.80(C), the OARRS data provided to McKesson was de-identified and did not provide pharmacy names and addresses, physician's names and contact information, or any patient identifying information. This "research extraction" has been shared within the MDL with other defendants. Earlier in the MDL, the Board came before this Court on a mandamus that was granted but was subsequently determined to be moot. *See In re: State of Ohio Board of Pharmacy*, Case No. 20-3375.

The research extraction included many of the database fields. And for some of the fields, a randomized "hash" was given to each individual patient, along with separate "hash" fields for prescriber names and pharmacy names. Here is a single entry of the research extraction provided to the Defendants:<sup>2</sup>

DateFilled	01/01/2015
RxNumber	123456
RefillCode	0
Quantity	30
DaysSupp	30
NDC	54092038101
Drug	ADDERALL XR 5 MG CER
TherClassCode	2820040010
TherClassDesc	Amphetamine & Comb.
DateWritten	01/01/2015
NumOfRefillsAuth	0
PaymentType	4

<sup>&</sup>lt;sup>2</sup> This is based on an actual prescription. Out of an abundance of caution, counsel has randomized the date the prescription was written and filled, the RX number, the zip code, and for the unique identifiers, changed any numbers to a 1 and any letters to an A. The extraction provides the first three numbers of a zip code. The research extraction provided information for all available fields the Pharmacy Defendants requested, although some of the fields were provided in de-identified fashion.

PharmacyHash	1111AAAAA11AA1111A11AA1AA11AA1111AAAA
	A
PharmacyZip	445
PharmacyBACCode	A
PharmacyBACSubCo	3
de	
PrescriberHash	1AA11AA111A1111AA111111AA11A1111111AA111
	A1
PrescriberZip	445
PrescriberBACCode	C
PrescriberBACSubCo	
de	
PrescriberSpecialty	Pediatric medicine
PatientGroupIDHash	A1A1111A11111A11AAAAAAAA1AA11111A11111A
	11A1
PatientAge	8
PatientSex	2
PatientZip	445

Using the unique "hash" for each patient, the Pharmacy Defendants can sort the entire database by patient. This "hash" will be identical for a specific patient for all of that patient's transactions in the database. Thus, the Pharmacy Defendants can identify every prescription filled for a specific patient that is stored in OARRS – but they would not know the name of the patient. The Pharmacy Defendants could do the same for the pharmacies and prescribers – again, without knowing their name, as there is also a hash assigned to each pharmacy and prescriber.

#### **III.** Statement of the Case

### A. Procedural History

Manufacturers and distributors of opioids are currently defending against a broad range of lawsuits brought by numerous public entities. Claims by nearly 2,000

political subdivisions have been consolidated in the U.S. District Court for the Northern District of Ohio as the MDL matters. This mandamus relates to "Track Three Cases" that involve Lake and Trumbull Counties in Northeast Ohio.

In June 2020, a number of large pharmacy companies<sup>3</sup> that operate in Northeast Ohio served a subpoena on the Board requesting the names and addresses of the pharmacies and prescribers.<sup>4</sup> A true and accurate copy of the Subpoena is attach as Exhibit "A." Upon receipt of the subpoena, the Board communicated with the Pharmacy Defendants that it would not be responding to the subpoena for the same reasons that were argued at length in the earlier MDL motions and mandamus action.<sup>5</sup> The Board and the Pharmacy Defendants agreed to a procedure involving the Pharmacy Defendants filing a Motion to Compel.

<sup>&</sup>lt;sup>3</sup> The defendants at issue are CVS Rx Services, Inc. CVS Indiana, LLC, CVS Pharmacy Inc. and Ohio CVS Stores, LLC, Rite Aid of Maryland, Inc. Rite Aid Hdqtrs. Corp., Walgreen Co., Walgreen Eastern Co., HBC Service Company, Giant Eagle, Inc., Discount Drug Mart, and Walmart Inc. For the purposes of this filing, they will collectively be known as the "Pharmacy Defendants."

<sup>&</sup>lt;sup>4</sup> The identity of the pharmacies and prescribers are provided by a unique identifying number but not by actual name.

<sup>&</sup>lt;sup>5</sup> This is the second time that this issue has been before this Court. In the Track One-B litigation, the Pharmacy Defendants requested the same OARRS data from the Board to defend against a claim that they had improperly dispensed opioids. Judge Polster granted a motion to compel, requiring the Board to turn over OARRS data. The Board filed a petition for a writ of mandamus which quickly became moot. *See In re: State of Ohio Board of Pharmacy*, Case No. 20-3375. In related litigation, this Court held that it had been an abuse of discretion for the district court in the Track One-B cases to allow dispensing claims against the Pharmacy Defendants. *In re Nat'l Prescription Opiate Litig.*, 956 F.3d 838 (6<sup>th</sup> Cir. 2020). In light of that order,

On July 1, 2020, the Pharmacy Defendants filed a motion to compel against the Board to produce the identifying materials from the OARRS database requested in their subpoena. A true and accurate copy of the Motion to Compel (MDL Doc. # 3364) is attached as Exhibit "B." Specifically, the Pharmacy Defendants want to show "widespread alternative causes of the alleged nuisance, e.g., the large number of 'over-prescribers,' 'pill mills,' and other dispensers" and to "identify doctor shoppers." Since the research extraction provided by the Board earlier in the MDL allows the Pharmacy Defendants to do this, the Board rightfully objected to this unnecessary and prohibited production of confidential and privileged data as set forth in the Board's Memorandum in Opposition to the Motion to Compel. A true and accurate copy of the Board's Memorandum in Opposition (MDL Doc. # 3380) is attached as Exhibit "C." Over the Board's objection, the district court granted the motion to compel on July 24, 2020. True and accurate copies of the Pharmacy Defendants' Reply Memorandum (MDL Doc. # 3391) and the district court's order (MDL Doc. # 3395) are attached as Exhibits "D" and "E," respectively.

In granting the motion to compel, the district court incorrectly held that (1) the Pharmacy Defendants have demonstrated their need for the identifying information, (2) there is no likelihood of invasion of patient privacy, and (3) there is

Judge Polster withdrew the order to turn over OARRS data in the Track One-B litigation.

no privilege that applies to the data. Therefore, the district court directed that the Board must produce the identifying information.

### **B.** The Arguments Before the District Court

The Pharmacy Defendants' subpoena sought the entire, identified, OARRS database. See Exhibit A. Relevant here, the Pharmacy Defendants wanted:

Prescription data from the Ohio Automated Rx Reporting System ("OARRS") for the following prescription drugs, to the extent oxycodone, hydrocodone, hydrophone, available: fentanyl, oxymorphone, morphine, methadone, and tapentadol, alprazolam, chlordiazepoxide, clobazam, clonazepam, clorazepate, diazepam, estazolam, flurazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam, carisoprodol, cyclobenzaprine, orphenadrine, and tizanidine. For each prescription, identify the drug name, prescription number, NDC number, date filled, quantity dispensed, dosage form, days' supply, MME, prescriber's name, prescriber's DEA number, dispensing pharmacist, dispensing pharmacy, patient's unique identification number, patient's state of residence, number of refills authorized (if any), diagnostic code, method of payment, patient paid amount, whether the prescription was covered by third party payers, and any other fields identified following a meet and confer with counsel for the Pharmacy Defendants.

Exhibit A, p. 11 (emphasis included)<sup>6</sup>.

This was almost identical to a subpoena issued by the Pharmacy Defendants in Track One-B cases involving Cuyahoga and Summit Counties. The Pharmacy Defendants and the Board agreed that the normal process of sending objection letters

<sup>&</sup>lt;sup>6</sup> The emphasized items represent the information the Pharmacy Defendants requested in de-identified fashion and to which the Board objected.

would be superfluous and it would be most appropriate to simply suggest a briefing schedule to the district court. Accordingly, the parties filed their respective motions.

The Pharmacy Defendants expressly stated that they were seeking OARRS data from 2006 onward in order to identify individual patients – albeit in deidentified fashion. "The OARRS data is also necessary to identify 'doctor shoppers." Exhibit B, p. 8. The Pharmacy Defendants emphasized that:

OARRS is the only dataset anywhere that allows the tracing of individuals across prescribers and pharmacies. Therefore, it is the only dataset that allows the identification of doctor shoppers who sought pills from multiple places, as well as the over-prescribers who wrote those patients' prescriptions. Identifying those patients and prescribers is a primary purpose of OARRS.

Exhibit B, p. 11 (emphasis in original).

In its opposition to the Motion to Compel, the Board objected to the subpoena because the information requested (including the identity of licensees) is confidential and privileged under state and federal law, that the de-identified information in the Pharmacy Defendants' possession is sufficient, and they could easily reverse engineer the database if they received the identifiers for the pharmacies and prescribers in order to identify individual patients. Exhibit C, pp. 5-11.

On July 24, 2020, the district court granted the Pharmacy Defendants' motion to compel. Exhibit E. The district court determined that the Pharmacy Defendants need for the identifying information outweighs any countervailing concerns of the Board related to the identification of the patient and that the information is not

confidential or privileged under state or federal law. Exhibit E, p. 6. Finally, the district court noted that the State of New York had turned over the names of prescribers and pharmacies from its own PDMP, leading it to conclude that "OBOP's concerns about privacy and statutory restrictions are overblown." Exhibit E, p. 6, fn 8. The district court did *not* directly address the Board's argument that O.R.C. 4729.80 makes the identities of licensees in OARRS privileged, nor did it address the Board's argument that the de-identified data already in the Pharmacy Defendants' possession provide the information that the Pharmacy Defendants need.

#### IV. Argument

#### A. Standard of Review

An appellate court has the power under 28 U.S.C. § 1651(a) to issue a writ of mandamus directing the conduct of a district court where (1) the petitioner has a "clear and indisputable" right to relief; (2) there are "no other adequate means to attain the relief"; and (3) mandamus relief is otherwise "appropriate under the circumstances." *Cheney v. United States Dist. Court D.C.*, 542 U.S. 367, 380-81 (2004). In short, only "exceptional circumstances amounting to a judicial 'usurpation of power" or a "clear abuse of discretion" will "justify the invocation of this extraordinary remedy." *Id.* at 380.

In an effort to distinguish between "errors that are merely reversible and not subject to mandamus, and those errors that are of such gravity that mandamus is

proper," this Court balances five factors: (1) whether the petitioner has no other adequate means to obtain the relief he seeks; (2) whether he "will be damaged or prejudiced in a way not correctable on appeal"; (3) whether "the district court's order is clearly erroneous as a matter of law"; (4) whether "the district court's order is an oft-repeated error, or manifests a persistent disregard of the federal rules"; and (5) whether "the district court's order raises new and important problems, or issues of law of first impression." *John B. v. Goetz*, 531 F.3d 448, 457 (6th Cir. 2008). "These factors need not all be met, and some factors will often be balanced in opposition to each other." *Id.* Although the standard for mandamus is, and should be, a high one, it is satisfied in the extraordinary circumstances presented here. Indeed, the first, second, third, and fifth factors all weigh heavily in favor of issuing mandamus.

# B. The Board Has No Other Adequate Means to Attain Relief and Will Be Damaged in a Way Not Correctable on Appeal.

It is well established that a party will satisfy the first two elements of mandamus when it is appealing a court order requiring the disclosure of confidential or privileged information. This Court has held that "mandamus may be used as a 'means of immediate appellate review of orders compelling the disclosure of documents and information claimed to be protected from disclosure by privilege or other interests in confidentiality." *John B.*, 531 F.3d at 457 (6<sup>th</sup> Cir. 2008) (quoting *United States ex rel. Pogue v. Diabetes Treatment Centers of Am., Inc.*, 444 F.3d 462, 472 (6th Cir. 2006)).

This is a classic example. The Board is *not* a party to the litigation – it is involved solely because the Pharmacy Defendants are seeking discovery from it. The Board cannot seek an immediate appeal under the "collateral order" doctrine under 28 U.S.C. §1291. *Mohawk Indus. v. Carpenter*, 558 U.S. 100, 103 (2009). "Mandamus must issue or [the Board] will be obliged to obey the binding court order[.]" *In re Lott*, 424 F.3d 446, 450 (6th Cir. 2005). If this Court does not halt the order to produce OARRS data, then the damage will be done and the confidentiality of the OARRS data will already have been lost. There will be no way for the Board to appeal once final judgment has been issued.

Moreover, the protective order issued in the district court does not guarantee the OARRS data will remain confidential. This Court has repeatedly held that the existence of a confidentiality agreement or protective order will not necessarily protect the data from being publicly available as a court record. Courts distinguish between limiting public disclosure of information during discovery versus the adjudicative stage of a case. *See Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016). "The line between these two stages, discovery and adjudicative, is crossed when the parties place material in the court record." *Id.* (citing *Baxter Int'l, Inc. v. Abbott Labs.*, 297 F.3d 544, 545 (7th Cir. 2002)). "Unlike information merely exchanged between the parties, '[t]he public has a strong interest in obtaining the information contained in the court record." *Shane Grp.*, 825 F.3d

at 305 (quoting *Brown & Williamson Tobacco Corp. v. F.T.C.*, 710 F.2d 1165, 1180 (6th Cir. 1983)). Thus, a party seeking to have its confidential information filed under seal has a "heavy" burden of overcoming a "strong presumption in favor of openness' as to court records." *Shane Grp.*, 825 F.3d at 305 (quoting *Brown & Williamson*, 710 F.2d at 1179) (explaining that only "the most compelling reasons can justify non-disclosure of judicial records" (citation and quotations omitted)).

Last year, this Court discussed the presumption in favor of openness of court records in a companion case, explaining:

The presumption in favor of openness of court records is justified because "[t]he public has an interest in ascertaining what evidence and records the District Court and this Court have relied upon in reaching our decisions." [Citations omitted]. This strong presumption in favor of openness is only overcome if a party "can show a compelling reason why certain documents or portions thereof should be sealed, [and] the seal itself [is] narrowly tailored to serve that reason." [Citations omitted]. Further, "the greater the public interest in the litigation's subject matter, the greater the showing necessary to overcome the presumption of access." [Citations omitted].

In re Nat'l Prescription Opiate Litig., 927 F.3d 919, 939 (6th Cir.2019) (emphasis added) (quoting Shane Group, Inc. v. Blue Cross Blue Shield of Mich., 825 F.3d 299, 305 (6th Cir.2016)). This Court concluded "[w]e therefore vacate any district court orders to the extent they permit sealing or redacting of court records." *Id.* at 939. Thus, the mere existence of a protective order is not sufficient to protect the OARRS data from possibly becoming accessible as a publicly available court record.

C. The District Court's Failure to Certify This Case for Immediate Appeal Under 28 U.S.C. §1292(b) Was Erroneous as a Matter of Law.

While discovery orders are generally not considered final for purposes of 28 U.S.C. § 1291, "this Court has authority to issue a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651" where "there is extraordinary need for review of an order before final judgment and the District Court has refused to certify the issue pursuant to § 1292(b)[.]" *In re Lott*, 424 F.3d at 449. Even if the district court did not agree with the Board's arguments it should have at least permitted the Board to appeal this critical confidentiality issue under 28 U.S.C. §1292 which states:

(b) When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order....

#### 28 U.S.C. §1292(b).

This Court has established that the "three factors that justify interlocutory appeal should be treated as *guiding criteria* rather than *jurisdictional requisites*." *In re Trump*, 874 F.3d 948, 951 (6th Cir. 2017) (quoting 16 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure §3930 (3d ed. 2002)) (emphasis in original). However, if a court finds that all three factors are present, a court has a

"duty . . . to allow an immediate appeal to be taken." *Ahrenholz v. Board of Trustees*, 219 F.3d 674, 677 (7th Cir. 2000). *See also In re Trump*, 928 F.3d 360, 369 (4th Cir. 2019) (same).

# 1. The District Court's Order Involves a Controlling Question of Law.

There is a clear controlling issue of law here. Under O.R.C. 4729.80, OARRS data (including the identity of licensees) is confidential and the Board is permitted to release information from OARRS only under several specific circumstances. It appears to be uncontested that the request here does not satisfy any of those specific circumstances. O.R.C. 4729.86(B) provides that "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." The controlling question of law is whether reading those two provisions together establishes that there is a privilege – notwithstanding the fact that the statutes do not use that specific term.

# 2. There are Substantial Grounds for Difference of Opinion about the Controlling Issue of Law.

This Circuit has adopted the legal standards of the Ninth Circuit for determining whether there is a substantial ground for difference of opinion. *In re Trump*, 874 F.3d 948, 952 (6th Cir. 2017). The question is whether "reasonable jurists might disagree on an issue's resolution, not merely where they have already disagreed." *Id.* (quoting *Reese v. BP Exploration, Inc.*, 643 F.3d 681, 688 (9th Cir.

2011). So a "novel issue may be certified for interlocutory appeal without first awaiting development of contradictory precedent." *Id.* (quoting *Reese*, 643 F.3d at 688). Here, a reasonable jurist could conclude that Ohio law bars the disclosure of the OARRS data.

Under O.R.C. 4729.80, the Board is permitted to release information only under several specific circumstances. While there is a provision that authorizes the Board to comply with a court order "in connection with the investigation or prosecution of a possible or alleged criminal offense" (O.R.C. 4729.80(A)(4)) and a provision for responding to grand jury subpoenas (O.R.C. 4729.80(A)(3)), there is no provision for such disclosure in a civil case.

Ohio law regarding the admissibility of OARRS information in civil cases cannot be clearer: "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B). Under O.R.C. 4729.86(A)(1), it is unlawful to improperly disseminate information from the OARRS database except for the limited exceptions listed in O.R.C. 4729.80(A) and (B). Improper disclosure of OARRS data is a criminal offense under O.R.C. 4729.99. There is no grant of immunity nor protection that can be afforded to the Board's Executive Director or

Director of the OARRS database for disclosing OARRS content other than for express purposes set forth in the governing confidentiality statutes.<sup>7</sup>

The district court's order expressly requires the Board to disclose the names of pharmacies and prescribers. This order flatly contradicts an Ohio statute which expressly prohibits the Board from releasing information which will "identify a person, *including any licensee* or registrant of the board or other entity[.]" O.R.C. 4729.80(C) (emphasis added). The Board licenses Ohio pharmacies. *See* O.R.C. 4729.01(Q) (definition of terminal distributor of dangerous drugs includes pharmacies) and 4729.54 (terminal distributors must obtain a license). Individuals who prescribe controlled medications are licensed by various entities including the State of Ohio Medical Board (O.R.C. 4731.09 and 4730.10), the Ohio Board of Nursing (O.R.C. 4723.41), the Ohio State Dental Board (O.R.C. 4715.10), and the Veterinary Medical Licensing Board (O.R.C. 4741.11).

In its Order granting the Pharmacy Defendants' Motion to Compel, the district court cited a number of cases where courts held statutes designating information as "confidential" is not the same as creating an evidentiary "privilege." Exhibit E, pp.

<sup>&</sup>lt;sup>7</sup> The Ohio Supreme Court has held that "a third party can be held liable for inducing the unauthorized, unprivileged disclosure of nonpublic medical information" and that "it is for the patient—not some medical practitioner, lawyer, or court—to determine what the patient's interests are with regard to personal confidential medical information." *Biddle v. Warren Gen. Hosp.*, 86 Ohio St.3d 395, 408, 715 N.E.2d 518, 528 (1999).

7-8. The district court added that if the Ohio "General Assembly *intended to create* an evidentiary privilege, it easily could have done so in express terms." Exhibit E, p. 8 (emphasis added). However, the district court ignored the language in O.R.C. 4729.80 and 4729.86(B), which distinguishes this matter from the cases on which the district court relied. Through those statutes, the Ohio General Assembly not only expressly provided that the OARRS data is confidential, it also, "in express terms," provided that the data cannot be used "as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B) (emphasis added). Thus, despite the district court's finding to the contrary, the Ohio General Assembly did indeed intend to "create an evidentiary privilege" by expressly stating the OARRS data could not be used as evidence. The fact the statute does not actually use the phrase "privilege" is of no consequence. Based on the foregoing, the second element of §1292(b) is present.

## 3. The Disclosure of OARRS Data Involves a New Legal Issue and is of Special Consequence.

The United States Supreme Court has implicitly established that the third factor under §1292(b) is met when an entity is raising a privilege claim that either involves a "new legal issue" or is "of special consequence."

The preconditions for §1292(b) review -- "a controlling question of law," the prompt resolution of which "may materially advance the ultimate termination of the litigation" -- are most likely to be satisfied when a privilege ruling involves a new legal question or is of special

consequence, and district courts should not hesitate to certify an interlocutory appeal in such cases.

*Mohawk Indus.*, <u>558 U.S. at 110-111</u>.

The issue about OARRS and whether the OARRS confidential data is privileged is both a novel legal issue and a matter of special consequence. While the issues about the application of Fed. Evid. R. 501 are not novel, the actual application of that rule to O.R.C. 4729.80 and 4729.86 as it relates to a determination of privilege is completely new. No federal courts have required the Board to turn over information from the OARRS database in a federal civil proceeding.

The matter is also of special consequence. Revealing the unique identifying numbers for each and every pharmacy and prescriber to the Pharmacy Defendants would not only be a violation of Ohio's confidentiality protections for licensees, which are expressly identified in the confidentiality codes, it would also be tantamount to providing the Pharmacy Defendants with the unique identifying numbers of individual patients for well over half of all Ohioans.

The breadth of information that is contained in the OARRS database cannot be overstated. This is not the private medical information for a single patient – or even every patient who saw a single doctor. These are the private medical records of over seven million people. The information would permit the Pharmacy Defendants to unlock the identity of millions of people's prescribing history. The Pharmacy Defendants did not dispute that this information could be used in this

fashion and the district court did not disagree. Instead, the district court stated that the Pharmacy Defendants (who had asked for the data, in part, to identify "doctor shoppers") would not be permitted to reverse engineer the data.<sup>8</sup>

Notably, the district court did not place any limits at all in its order as it relates to pharmacies or prescribers. The order is not limited to only a specific time frame, or those that prescribed or dispensed to patients from Northeast Ohio. It also is not limited to prescription opioids. Medicines like testosterone cream, Ambien, Xanax and Ritalin are also controlled substances under Ohio and federal law and are wholly included in the data. These drugs are not part of these lawsuits, but under the court's *carte blanche* order, the Pharmacy Defendants will be able to discover all of that information. Put another way – this is not just any old discovery fight. This is clearly a matter of "special consequence."

# D. In the Alternative, the District Court's Order was Clearly Erroneous as a Matter of Law.

This Court also has the option of ruling on the underlying merits because the Board has a clear and indisputable right to relief. The district court erred as a matter of law, when it refused to apply Ohio confidentiality laws without an identification of a specific privilege. Even aside from the statutory prohibition, the district court

<sup>&</sup>lt;sup>8</sup> Despite the Pharmacy Defendants having been ordered to not, and their assurances that they will not, reverse engineer the data to identify patients, this does not change the fact that it can be done. This precedent should not be set.

abused its discretion in ordering the disclosure of such vast swaths of the OARRS database with insufficient protections.

# 1. The District Court Abused Its Discretion In Failing To Find That Ohio Law Makes This Information Privileged.

Although the district court held that the Board "is generally correct regarding application of state law privileges in federal cases based on diversity jurisdiction" it failed to apply those to this matter because it found that the Board failed to "show [that] a specific state law privilege exists that governs this precise issue." Exhibit E, p. 7. This Court's binding precedent establishes that under Fed. R. Evid 501, federal courts apply a state's confidentiality laws if the case is being heard under diversity jurisdiction. *See Jewell v. Holzer Hosp. Found., Inc.*, 899 F.2d 1507, 1513 (6th Cir. 1990); *Jaffee v. Redmond*, 518 U.S. 1, 15 (1996). The Track Three case is proceeding solely under a common law claim of nuisance under Ohio law.

As noted above, the district court ordered the Board to provide the identities of pharmacies and prescribers in the OARRS database. But Ohio law forbids the Board from releasing information in the OARRS database about "any person" – including licensees, which is information the district court ordered the Board to produce. Unless one of the exceptions of O.R.C. 4729.80(A) or (B) apply, the Board is simply not permitted to release information from OARRS that will "identify a person, including any licensee or registrant of the board or other entity[.]" O.R.C.

4729.80(C). That includes pharmacies (who are licensed by the Board) and prescribers (who are licensed by an "other entity"). And while OARRS data can be provided in a criminal case under O.R.C. 4729.80(A)(3) and (4), there is no comparable provision for civil cases.<sup>9</sup> On the contrary, "A person shall not use information obtained pursuant to division (A) of section 4729.80 of the Revised Code as evidence in any civil or administrative proceeding." O.R.C. 4729.86(B).

But the order goes further than just the names of pharmacies and prescribers. Here, the district court ordered the Board to provide the Pharmacy Defendants with all the tools they would need to easily determine patients' identities. The Pharmacy Defendants are the biggest pharmacy chains in Northeast Ohio. They have extensive databases detailing what medications they have dispensed to patients. Providing them with the identity of all prescribers and pharmacies for each prescription listed in the research extraction (which the Defendants already have received) will essentially provide the Pharmacy Defendants the identities of countless patients in the OARRS database with only a modicum of reverse engineering.

For example, if Walgreens (one of the Defendants) was supplied with all information for a particular prescription that was filled at a Walgreens pharmacy – the prescription number, drug prescribed, the date the prescription was written, the

<sup>&</sup>lt;sup>9</sup> Notably, even for criminal cases, there is not carte blanche for broad swaths of the database. O.R.C. 4729.80(A)(3) is limited to searches "relating to the person who is the subject of an investigation being conducted by the grand jury."

date the prescription was filled, quantity, number of refills, prescriber name, and specific pharmacy name and address at which the prescription was filled – Walgreens could easily locate that particular prescription within its records. Walgreens' records would necessarily include the patient name for the prescription, thus, revealing the identity of that patient. Walgreens would then know the unique identifying number for that patient.

Walgreens would then be able to search the database by that patient's unique identifying number to discover every single purchase that patient ever made at *any* pharmacy (not just Walgreens) even years before or years after that patient was a Walgreens customer. The district court addressed these concerns by simply stating in its order that the Pharmacy Defendants would be forbidden from reverse engineering the information. But if the data can be used to "identify a person" then it is barred from disclosure by O.R.C. 4729.80(C), even if the Pharmacy Defendants promise that they won't peek behind the curtain (notably, they expressly asked for the data in order to identify which patients are "doctor shoppers").

Further, if the Pharmacy Defendants intend on using the information obtained from OARRS to support their defense at trial or in dispositive motions, the information would become a court record. As previously discussed, documents and information used to support a claim or defense will likely be publicly accessible as a court record. *See, In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919, 939 (6th

Cir.2019). Instead of evaluating Ohio's confidentiality laws, the district court concluded that the Board's "concerns about privacy and statutory restrictions are overblown" because the State of New York provided analogous data voluntarily. Exhibit E, p. 6, footnote 8. The Board has *never* claimed that Ohio's statutes would apply to the State of New York.<sup>10</sup> New York's decision to <u>voluntarily</u> produce its own information is indicative of nothing and certainly cannot be used as the basis for compelling an Ohio agency to produce information in violation of state law.

In the end, the district court abused its discretion in granting the motion to compel production from the OARRS database.

## 2. The Pharmacy Defendants Already Have the Information In De-identified Format.

The district court also abused its discretion by holding that the Pharmacy Defendants have demonstrated their need for the identifying information and there is no likelihood of invasion of patient privacy. The district court in this case emphasized that it believes that the Pharmacy Defendants will not need the names of individual patients in order to present their case because they can "utiliz[e] OBOP's de-identified patient ID number." Exhibit E, p. 5. Yet, the district court

<sup>&</sup>lt;sup>10</sup> Although New York's confidentiality statute, 10 NYCRR 80.107 is similar in some respects to O.R.C. 4729.80, Ohio's statute is much more detailed. Most importantly, as discussed repeatedly above, O.R.C. 4729.86(B) specifically prohibits the use of OARRS data in a civil proceeding. The Board is unaware of any similar prohibition in New York law.

held that the Pharmacy Defendants "cannot pursue a potential defense without actual identities [of the pharmacists and prescribers] contained in the OARRS data fields they seek" and that "the relevance for the data is clear." Exhibit E, pp. 4, 6.

Neither the Pharmacy Defendants nor the district court explained why using the de-identified pharmacy ID numbers and prescriber ID numbers in the research extraction is insufficient. The only thing that the Pharmacy Defendants will not specifically know will be the name of the actual prescriber or pharmacy. They still have the ability to use the unique identifiers to identify problematic prescribing or dispensing habits to use as their defense. If the Pharmacy Defendants' "aim" is to "identify alternative causes of the alleged nuisance," the Pharmacy Defendants do not need the specific identities of prescribers – just as they do not need the specific identities of patients to uncover "doctor shoppers." To accomplish their aim, the Pharmacy Defendants can examine prescribing habits of prescribers by their unique number to demonstrate there are prescribers who are over prescribing opioids. For example, if prescriber number "2020" has a history of prescribing opioids in significantly greater numbers than other prescribers, the Pharmacy Defendants can point to prescriber "2020" and any other prescribers with a similar history as an "alternative cause" of the "alleged nuisance." The Pharmacy Defendants have not explained how having the actual name of the prescriber will bolster their defense.

In addition to already being able to identify prescribers and pharmacies with a unique hash, the Board annually produces data detailing doctor shopper statistics in its reports. Those documents were requested and produced as part of the same subpoena at issue here. Moreover, those documents are readily available on the Board's website and are a viable alternative should the Pharmacy Defendants seek to use information pertaining to doctor shoppers in its case, see for example https://www.ohiopmp.gov/documents/Annual%20Report%20(2018).pdf.<sup>11</sup>

### E. The District Court's Order Raises New and Important Problems.

As discussed in more detail above, the scope of the discovery being required is immense; it will require the disclosure of information about prescriptions filled for over seven million people. At the risk of repetition – if this order does not "raise new and important problems," it is difficult to imagine any discovery order that does. The fifth factor of mandamus strongly weighs in the Board's favor.

# V. This Court Should Stay Enforcement of the District Court Order to Compel Production.

Under Fed. R. App. Proc. 8(a)(2), this Court has discretion to grant a stay or injunction. This Court reviews four factors: (1) whether a party has made a strong showing that it is likely to succeed on the merits; (2) whether it "will be irreparably injured absent a stay;" (3) "whether issuance of the stay will substantially injure the

<sup>&</sup>lt;sup>11</sup> A copy of the document from this link is attached as Exhibit "F."

other parties interested in the proceeding;" and (4) "where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). "These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Michigan Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991). The first two factors are the most critical. *Nken*, 556 U.S. at 434.

#### Likelihood of success on the merits.

The Board has made a strong showing that it will prevail on the merits. It has identified binding case law that mandates that district courts apply state confidentiality laws when hearing cases that involve only state law claims. The Ohio laws at issue are clear and unambiguous. At the very least, the district court should have certified this matter under 28 U.S.C. §1292(b) so that it could be reviewed further. The Board has a strong likelihood of success on the merits.

### Irreparable harm.

It is well established in this Circuit that the disclosure of privileged information is a form of irreparable harm. If a party "is wrongfully forced to disclose privileged communications, there is no way to cure the harm done to [the party] or to the privilege itself, even if some of the disclosure's consequences could be remedied on direct appeal." *In re Lott*, 424 F.3d 446, 452 (6th Cir.2005). Put another way: "privilege operates to prevent the disclosure itself." *Id.* at 451.

#### Harm to Third Parties and the Public Interest.

The OARRS data at issue includes medical records for the majority of Ohioans. For normal cases, a court order stating that information will remain private will be sufficient. But this is not just any ordinary case. This is a massive MDL with multiple defendants who have untold numbers of lawyers, experts and consultants – all of whom would be able to peruse the OARRS database with only a small amount of research. And the scope of the documentation makes it different from any typical discovery issue.

Because this is the entire database for millions of Ohioans, the interest of third parties and the public at large would be to grant the stay even if there was only a small chance of success – as opposed to the overwhelming case that the Board is bringing.

#### VI. Conclusion

For the forgoing reasons, the Board respectfully requests that this Court grant a writ of mandamus against the District Court for the Northern District of Ohio requiring it to deny the Defendants' Motion to compel. Alternatively, this Court should require the district court to certify its granting of Defendants' Motion to Compel for interlocutory appeal. In addition, the Board asks that this Court stay its requirement to comply with the order to compel while this matter is pending.

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#### **CERTIFICATE OF SERVICE**

Service on counsel for all parties in the district court has been accomplished via notice filed through the district court's CM/ECF system attaching a copy of this filing on August 19, 2020.

/s/ Kevin L. Murch
Kevin L. Murch (0066833)